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Abstract:

INTRODUCTION. Communication between physician and patient is very important to allow the patient to make a well-informed health care decision. Evidence-based medicine is one approach in which medical information can be presented by a health care professional. This study was designed to gather data relating to a patient's understanding of information, specifically evidence-based medicine, provided by a physician.

METHODS. Approximately forty patients with chronic conditions or parents of young patients with chronic conditions were identified through an existing database. Thirty brief phone interviews were completed to determine an initial patient understanding of evidence. The responses from the phone interviews were analyzed to divide the twenty-six willing participants into two focus groups of approximately equal members. Further data collection regarding patient understanding of evidence-based medicine was gathered in these two separate focus groups.

RESULTS. Based upon the results of our phone interview questionnaire and focus groups, the participants in this study fell into one of two categories: statistics oriented and relationships oriented. The statistics oriented group included those participants who wanted all the facts in order to be the primary decision maker while the physician served as an assistant in the process. The relationships oriented group participants tended to desire just a summary of the facts to assist the physician in making the decision.

CONCLUSION. Patients cannot be divided into groups, but tend to fall along a spectrum. Patients falling in different areas of the spectrum may desire different levels of evidence. Physicians must realize that no set script can be used for every patient; however a flow chart of questions to ask and key phrases to listen for may be helpful for the physician to determine what information the patient needs in order to make a health care decision.

COMMUNICATION OF EVIDENCE-BASED MEDICINE

**A PROJECT REPORT
SUBMITTED TO THE FACULTY OF
THE DEPARTMENT OF PREVENTIVE MEDICINE AND BIOMETRICS OF
THE UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
BY**

**MELINDA EATON, DVM
CAPT, BSC, USAF**

**IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF
MASTER OF PUBLIC HEALTH**

**PROJECT MENTOR:
VIRGINIA F. RANDALL, MD, MPH, COL, MC, USA**

JUNE 2004

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Introduction:

Communication between a physician and a patient is the basis of public health. A physician must be able to approach a patient with the desired amount and type of evidence necessary to enable the patient to make a well-informed health care decision. For example, a physician must provide a mother/father with adequate information to persuade them to properly immunize their child. If a failure in communication between a patient and physician occurs, then disaster can result (i.e. vaccine-preventable death or outbreak). Good communication between the physician and the patient gives the patient the ability to share in their own health care decisions (i.e. take part in the decision-making process or shared decision making). A number of models have been developed to describe this decision-making process.¹⁻³ These models describe the interaction between the patient and the physician, however they do not present specific ways in which a physician can present information which the patient can utilize while making a health care decision.

Evidence-based medicine is one approach in which medical information can be understood and presented by a health care professional.^{4,5} This approach involves the use of numeric and factual data from clinical research to influence a health care decision. Studies have shown that patients are not receiving enough information from their physician in order to make a well-informed health care decision.⁶⁻⁹ Additionally, patients may become confused by the presentation of the evidence whether in numeric or descriptive format.⁸⁻¹¹ Physicians may be forcing patients to quickly make important health care decisions without determining if the patient completely understands the evidence that has been presented to them.⁸ Few studies have been conducted to ascertain the patients' understanding of evidence. A needs assessment is

necessary to determine what evidence a patient desires to enable them to make a well-informed health care decision.

This study was designed to gather data relating to a patient's understanding of information, specifically evidence-based medicine, provided by a physician. This study aimed to answer the following research question: Among patients with a chronic condition or parents with children having a chronic condition, how is the concept of "evidence-based medicine" understood and how can this understanding be portrayed to physicians to ensure that parents and patients are presented with the type and amount of evidence that they want?

The specific objectives of this study designed to address the research question were:

1. Determine the patients' meaning of the word 'evidence'.
2. Determine what evidence the patient wants when presented with a health care decision.
3. Develop guidelines relating to presentation of evidence-based medicine to be incorporated in medical school curriculum.

Methods:

Approximately forty patients with chronic conditions or parents of young patients with chronic conditions were identified through an existing database from the Pediatrics Department of the Uniformed Services University of the Health Sciences. Each individual in the database had previously given informed consent for participation in phone interviews and focus groups addressing professionalism and physician-patient communication. Thirty brief phone interviews were completed to determine an initial patient understanding of "evidence" (see questionnaire

created by Virginia Randall, Bradford Lang, and myself in appendix 2). The responses from the phone interviews were analyzed to divide the twenty-six willing participants into two focus groups of approximately equal members, based on a qualitative analysis of their definitions of “evidence”. Thirteen participants were able to attend the focus groups on the arranged dates and times. One additional participant attended each focus group. The first focus group had ten participants and the second focus group had five participants.

Further data collection regarding patient understanding of evidence-based medicine was gathered in these two separate focus groups. The focus groups were conducted with two trained facilitators as well as two note-takers. A tape recorder was used in the first focus group; however the tape was not audible and thus not used in the second focus group. The focus groups were conducted using a structured approach with open-ended questions (see focus group guide created by Virginia Randall and Janice Hanson in appendix 3). Individual responses were collected on note cards while group discussion was written on a paper flip chart. Descriptive analysis of the data was performed independently by three members of the research team. The individual analyses were combined to form a collected interpretation of all gathered data (see summary of data analysis by Virginia Randall, Bradford Lang, and myself in appendix 4).

Results:

The initial phone interview questionnaire allowed for collection of key data used to divide the participants into two focus groups. The main focus of the questionnaire included the questions “If your doctor talked about evidence in relation to a health care decision, what do you think the word evidence means?” and “If you had to make a serious medical decision what kind of evidence would you want?”. Questions regarding health care needs, approximate length of

time dealing with health care needs, education levels, and occupation were also included to assess the comparability of the participants (see Table 1 in appendix 5).

Based on the data collected from the first two questions, two focus groups emerged. Participants placed into the first focus group tended to emphasize statistics while participants in the second focus group tended to emphasize relationships in the initial phone questionnaire. Those participants willing to participate in the focus groups were contacted and the focus groups were created (see Table 2 in appendix 5).

The focus groups were conducted using a facilitator's guide (see focus group guide in appendix 3). The responses to the questions were collected and analysis revealed the following results.

Initial perception of evidence:

After a brief introduction to evidence-based medicine was presented, participants were asked to provide an example of treatment advice and evidence given by a physician to corroborate the treatment advice. Most participants suggested the evidence given by the physician was in the form of experience and opinions; however three of the eleven responding participants did receive evidence that could be regarded as evidence-based medicine. Specifically mentioned by the participants were "protocols" and "case reports". This question was possibly biased by the topic of the discussion (evidence-based medicine) and the recollection of the participants based on their most memorable experience with the physician (i.e. best/worst case scenario).

Desired level of evidence:

The focus group participants were given a handout detailing the hierarchy of evidence (see focus group handouts created by Virginia Randall in appendix 6). After this information was presented, the participants were asked how much they wanted to know regarding the level of evidence that supports their physician's advice.

The first group wanted specific information related to the hierarchical level upon which the physician based his recommendation. Specifically one patient requested "If there are RCT's [randomized controlled trials]: statistically, what do the RCT's show and what do the systematic reviews show and does my specific case fit their guidelines and the studies that have been reviewed?" Another participant mentioned several questions including: "Where did he get the info from? Who sponsored it? How long did the study last?" Additionally, several participants asked for the physician's opinion in relation to the evidence they were presenting. Sample questions from the participants included: "How long have you been making treatment decisions based on the guidelines?" and "What would you ask your doctor if he gives advice?" As evident by the results gathered from this question, the primary theme of this first group was the intent to gather as much scientific information as possible regarding the decision to be made while secondarily seeking the physician's advice regarding this scientific information.

The second group also wanted scientific information, specifically "well-developed guidelines" in order to make a health care decision. However, only one individual particularly requested the physician's opinion regarding information received: "What benefit of this procedure and treatment regimen will I receive? What kind of success stories have you experienced?".

A follow-up question was posed to the participants to determine if a change in circumstances could alter the level of evidence that they desired. The first group strongly emphasized that their level of evidence desired would change in an emergency situation or “if we had tried other treatments without success”. Other participants indicated that they might be willing to alter the level of evidence desired if they had a “trusted relationship with physician” or “it would cause no harm to try”. A few participants would not be willing to change the level of evidence they wanted if it conflicted with their personal values.

In comparison, the majority of participants in the second group indicated that they would change the level of evidence they desired based on their trust and confidence in their physician. Specifically mentioned by the participants were the phrases “our decision is based on the trusting relationship between doctor and family” and “if it were an unknown doctor we might require more evidence based on not knowing doctors background enough”. Other participants suggested that taking their child’s opinions and desires into consideration might change the level of evidence desired.

Gap between evidence and patient values:

The participants were referred to the previously distributed handouts (see appendix 6) to discuss the gap between evidence and patient values. The participants were asked to relate other factors that were important when making a medical decision. They were asked to distinguish between medical decisions made when they were the patient vs. their child as a patient.

The first group seemed to focus primarily on family arrangements and care, such as “how will it impact my family functioning” and “emotional impact of illness on family”. Secondly this group focused on impact on them (i.e. follow-up care, convenience, and risk) when making a

health care decision for themselves. When making a health care decision for their child, this group emphatically focused on the theme that they would do whatever it takes to help their child. One participant mentioned "don't care if illegal" and another "don't mess with my child". When asked to rank order the top three factors most important to them for themselves, eight out of ten respondents mentioned family. In comparison, when ranking factors for their child, ten out of ten responses focused on some aspect of consequences such as "what if I don't do this" and "long term effect on quality of life".

The second group primarily focused on their relationship with the physician when making decisions for themselves. Examples given by the participants included "doctor's personality, rapport, professionalism, and trust". Secondly, this group focused on impact of the decision on family. Factors stated included "timing, wait until summer so burden is less on family, and convenience regarding family obligations". When making health care decisions for their child, this group focused on doing whatever it took to help the child, however this group valued the child's opinion in the decision making process and also impact to family and career. Comments from the participants such as "how much decision making I've transferred to child, children look at long term differently, and family quality of life" were declared during the focus group. When asked to rank order the top three factors most important to them for themselves, four out of five participants focused on factors affecting themselves, and fewer mentioned impact on family (three out of five) when compared to the first group. When developing a rank order for the child, four out of five focused on the doctor's opinion for the child, followed secondarily by some aspect of child's quality of life.

From our summary of data analysis (see appendix 4), both groups indicated some sort of risk/benefit analysis not as primary theme, but present in both listings for themselves. Both

groups also indicated whatever it would take for child as a primary theme. In contrast, while the second group emphasized the physician's characteristics as an important factor, only one person in the first group specifically mentioned practitioner.

Number Needed to Treat and Number Needed to Harm:

An explanation and definition of Number Needed to Treat (NNT) and Number Needed to Harm (NNH) was presented to the focus group participants as a way of balancing benefit and risk using the previously distributed handouts (see appendix 6). Participants were then asked if this explanation would help them make a medical decision. Combining the responses from both groups, a few indicated they would take it into consideration, but overall they did not appear to place much value in it. One participant stated that they "actually think NNT/NNH vs. benefits and risks would be confusing" while another said that "NNT and NNH are more "cumbersome" concepts". Most participants did want some form of discussion relating benefits and risks.

Participants were then asked how the physician could explain this concept in a way that made sense to them. Both groups agreed that the word "harm" should be replaced in discussions as "side effects". Most participants wanted to be given as much information as possible, regardless of their emotional state at the time. The majority also wanted the doctor to follow up after presenting the information to ensure that the patient understood and provide the patient with the opportunity to ask questions. One participant wrote the "ideal script" that they would like to be presented with "I'd like to share some evidence with you about your/your child's situation so you feel fully informed and we can come up with a good plan".

Balance and shared decision-making:

The participants were provided with a handout (see appendix 6) illustrating the concept of shared decision-making by balancing three factors: the doctor's clinical judgment, the evidence (both what works and risk), and the patient/family's values. Participants were asked to rank order these factors by level of importance to them. The responses were tallied and also weighted during the analysis. The overall ranking for the first group was evidence #1, doctor's judgment #2, and patient/family values #3. For the second group, evidence was either placed 1st or 3rd while doctor's judgment was placed 2nd and patient/family values was placed 3rd. However the ranking was less clear with this group, probably due to the smaller number of participants. Evidence was more important in the first group and factors rated relatively evenly in the second group. This question is problematic because the topic of evidence-based medicine previously discussed in the focus groups may have biased each group towards placing evidence near the top of the ranking.

Summative discussion:

A final set of questions was posed to the participants to gather an overall summary of each focus group.

1. What explanations of evidence do you want?

From the summary of data analysis (see appendix 4) it was determined that the major theme from both groups appears to be emphasis on risk v. benefit. The first group tended to stress the need for a thorough discussion including "I want a high level, intelligent explanation and I will ask clarifying questions that will demonstrate what I do and don't understand" and "all

the facts, all possible outcomes". The second group desired less detailed information, however two participants specifically requested handouts for future reference.

2. What do you want the doctor to ask you?

The first group requested that the doctor ask questions relating to their understanding of the material presented as well as probing the patients to see if they would like more information. One participant stated "Ask me if I'd like to be provided with research pointers or even if I wanted to know the keywords to use in a medicine search". In contrast, the second group did not focus on questions relating to the understanding of the material presented, but rather on the emotional impact of the decision of the patient. Participants indicated the importance of questions such as "What are my greatest fears and concerns?" and "How is this effecting daily life?".

3. What can you do to let the doctor know what you want?

Both groups indicated that they would speak openly to the physician to let them know what they want. However responses from the first group tended to indicate a more aggressive approach: "I can speak openly and honestly and not be confrontational to doctor" and "be firm and ask the doc in many ways until you get the answer/understand the treatment".

Discussion:

Based upon the results of our phone interview questionnaire and focus groups, the participants in this study fell into one of two categories: statistics oriented and relationships oriented. The statistics oriented group included those participants who wanted all the facts to be able to be the primary decision maker while the physician served as an assistant in the process. The relationships oriented group participants tended to want just a summary of the facts to assist

the physician in making the decision. At the extreme, this group may have had the tendency to rely solely on the physician for making a medical decision.

Previous studies describe a similar grouping process of patients. In a study published in 1956 by Dr. Thomas S. Szasz and Dr. Marc H. Hollender, three models were used to describe the physician-patient relationship.¹² These models included: the model of activity-passivity in which the patient is unable to respond to the physician, thus the physician is in control of all decisions; the model of guidance-cooperation on which the physician tells the patient what to do; and the model of mutual participation in which the physician and the patient work together to make a decision.¹²

In the early 1990s, another set of models was presented by Dr. Ezekiel J. Emanuel and Dr. Linda L. Emanuel.¹³ These models divided the patient and physician into four distinct groups based on their preferences and decision-making abilities. In this study the models were described as: the paternalistic model-the physician served to provide the patient with the information needed to ensure that they made the decision the physician felt was best; the informative model-the patient used their values to make a decision, however they are dependent on the physician to provide the facts necessary to make a decision; the interpretive model-the physician was aware of the patient's values and aimed to provide facts and assist the patient in making a decision based on these values; and the deliberative model-the physician served to assist the patient in selecting the values that are necessary to make the best medical decision.¹³

While these models differ from the two models in which our participants became grouped, some components are similar. The statistics group seemed to incorporate elements found in the informative, interpretive, and deliberate models while the relationships group incorporated elements of the paternalistic, deliberative, and interpretive models. However,

patients and physician cannot be easily separated into two, three, or even four distinct categories when making a decision or describing their relationship. There tends to be a spectrum in which patient and physicians fall with the majority falling somewhere in the middle and a few outliers at each extreme.

In an ideal setting, each patient could be identified from the first interaction with the physician as to what evidence they would like the physician to provide and the physician would be aware of the patient's values. A script could be drafted to be used in each situation to satisfy both the physician and the patient to ensure that the right combination of evidence and patient values are considered when making a medical decision.

However, this is generally not the case. A physician may present information that the patient does not understand or does not want and the patient may not express what values are important to them when conversing with a physician about a medical decision.

Physician-patient relationships should begin to be developed early in medical school to prevent these future physicians from being tunneled into using a set script for all patients. Communication using evidence-based medicine can be an essential part of this learning process. From the information gathered during the phone interviews and focus groups, a flow chart was drafted to be incorporated into the medical school curriculum (see flow chart in appendix 7).

The previously stated objectives were met throughout the course of this study. The patients meaning of the word "evidence" was determined partly through the use of the phone interviews as well as the first few questions addressed in the focus groups. The focus groups were also useful in presenting the hierarchy and levels of evidence that are available to the patients as well as allowing participants to focus on what types of evidence they desired.

Guidelines for the presentation of evidence-based medicine were drafted into a flow chart form based on the results of the focus groups and are included in appendix 7.

This study was strengthened by the caliber of the participants. Most of the participants were very familiar with the health care system and were willing to share their opinions about the interaction with physicians as well as provide suggestions about how to improve physician-patient communication. One limitation in this study was the small number of participants owing to focus group availability. It would be interesting to determine if those who participated in the phone interviews but not the focus groups had the same opinions as those who did participate in the focus groups.

Conclusion:

The data gathered from this study indicates that no two patients are alike in what evidence they desire and what values they feel are important in making a medical decision. Patients cannot be divided into two, three, or even four models, but tend to fall along a spectrum. Patients falling in different areas of the spectrum may desire different levels of evidence. A physician who interacts in the same manner and from the same script with each patient may be in fact alienating his/her patients. It is important for a physician to understand what evidence the patient wants and what values are important to them, as well as for the patient to be able to express their values to the physician. One way to help the physicians determine what their patients' desire is through the use of a flow chart (see appendix 7).

Further research is needed to determine additional key indicators that can be used as a guide (i.e. key phrases that a physician can listen for in a conversation with the patient) to enable the physician to present the patient with the level of evidence that they desire. Furthermore,

medical school curriculum could be designed to better provide the physician with an indication of where the patient falls along the spectrum of evidence and values so that they are able to learn to provide what each patient desires. The sample flow chart found in appendix 7 can be used as a rough draft to facilitate this process.

Contributors:

Dr. Virginia Randall served as project mentor and overall study coordinator along with Dr. Janice Hanson. Bradford Lang assisted with data collection and data analysis.

Acknowledgements:

This study would not have been possible without the assistance of Dr. Virginia Randall, Dr. Janice Hanson, Dr. Tomoko Hooper, Dr. Gary Gackstetter, Bradford Lang, and all the willing participants of the phone interviews and focus groups. Thank you for your help and participation.

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Appendix 1: IRB Approval



UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799



February 23, 2004

MEMORANDUM FOR CAPT MELINDA EATON, D.V.M., DEPARTMENT OF PREVENTIVE MEDICINE
AND BIOMETRICS

SUBJECT: Institutional Review Board (IRB) Approval of T087UL for Human Subject Participation

Congratulations! Your minimum risk research protocol T087UL, entitled "*Communication of Evidence - Based Education*," was reviewed and approved for execution on February 23, 2004 by Edmund G. Howe, M.D., J.D., Chairperson, Institutional Review Board, under the provisions of 45 CFR 46.110(b)(1)Suppl. F(7), FWA 00001628. **This approval expires on February 22, 2005.** You are authorized to enroll up to 40 subjects in this study. This approval will be reported to the full Uniformed Services University IRB scheduled to meet on March 11, 2004.

T087UL is a sub-study of Dr. Janice Hanson's G186FB, "Collaborative, Competency-Based Medical Education with Parents and Patients as Advisors." Capt Eaton is an associate investigator on G186FB. Protocol T087UL elaborates procedures defined in Amendment #1 to G186FB, approved on December 23, 2004. Data collection activities associated with this protocol were approved effective 23 December 2004, including phone and focus group interviews with 30-40 parents and patients who have previously consented to participate in the project.

Authorization to conduct this protocol will automatically terminate on February 22, 2005. If you wish to continue with data collection or analysis beyond this date, please submit a USU form 3204A/B (continuing/annual review) to the Office of Research by **December 24, 2004**. Though we will attempt to assist you by sending you a reminder, this reporting requirement is your responsibility.

You are required to submit amendments to this protocol, changes to the informed consent document (if applicable), adverse event reports, and other information pertinent to human research for this project to this office for review. No changes to this protocol may be implemented prior to IRB approval. If you have questions regarding specific issues on your protocol, or questions of a more general nature concerning human participation in research, please contact me at 301-295-3303 or rbienvenu@usuhs.mil.

Robert V. Bienvenu II, Ph.D.
MAJ, MS, USA
Director, Human Research Protections Program
and Executive Secretary, Institutional Review Board

cc: Director, Research Administration
Chair, PMB
File
Dr. Janice Hanson, PED
COL Virginia Randall, PED
DR. HODDER, PMB

Printed on Recycled Paper

Appendix 2: Phone Questionnaire

Patient ID#:

Date:

Time:

Hello my name is _____. I am an MPH student at the Uniformed Services University of Health Sciences working with Drs. Hanson and Randall on an HRSA grant to study how patients understand the meaning of words used by doctors and how information is communicated. I obtained your name and phone number from your consent to participate in this research study. We are conducting a survey that will be used to help us direct our study that normally takes approximately 10 minutes. If this is a convenient time for you, would you mind answering a few questions? I will keep hand written notes for reference, so I may pause occasionally between questions to complete them.

1. If your doctor talked about "evidence" in relation to a health care decision, what do you think the word "evidence" means?
2. If you had to make a serious medical decision, what kind of evidence would you want?
3. Please, briefly describe any special health care needs of you and your family and when they started?
- 4a. What level of education have you completed?
- b. If you have a spouse or a partner, what level of education have they completed?
- 5a. What is your occupation?
- b. If they have a spouse or partner (see 4 b): What is your spouse or partners occupation?
6. As part of our study we are planning to convene focus groups to investigate how patients understand the meaning of words used by doctors and how information is communicated.

If you were invited, do you think you would be interested in participating in a focus group?

Would you like feedback about this research?

Appendix 3: Focus Group Guide

Evidenced-Based Medicine (EBM) and Doctor/Patient Communication Focus Group Plans

Goals:

1. To describe how this group of patients understands evidence.
2. To describe what kinds of explanations from doctors would help this group of patients understand evidence more fully.
3. To obtain suggestions from this group of patients about how to include information from evidence-based medicine in shared decision-making discussions with patients.

Research Methodology:

Focus group with use of storyboard and flip chart to collect and organize participants' responses

Materials Needed:

Storyboard, push pins, 3x5 cards, markers, masking tape, pens, sign-in sheet, flip chart, handouts (levels of evidence, NNT and NNH, introduction to EBM, list of decision criteria to rank)

Focus Group Plan:

1. (10 minutes) Introductions
 - a. Post and explain the focus group goals to the group.
 - b. Ask group participants to introduce themselves briefly.
 - c. Provide a brief introduction to EBM.
 - i. We will be discussing how doctors think about evidence based medicine and how we can translate that in a way that makes sense to you. In evidence based medicine, a very specific question is asked relating to a decision such as diagnosis, treatment, or outcome. The physicians then uses a computer to access specialized databases to find the best evidence to aid in answering the question. The next step is translating that evidence into something that can be shared with the patient in a way that makes sense in a shared decision making context.
 - ii. We will only be exploring this topic, as it is huge. We have a series of questions to ask you, and will limit the discussion of each question to 15 minutes. This will be a much more structured focus group than you are used to. Sometimes we will be making lists on flip chart paper, other times we will use 3x5 cards to capture more complex ideas.
 - iii. We will be limiting our discussion of evidence based medicine to treatment decisions only.
2. (20 minutes) Elicit a short example of *treatment* advice and related evidence from each participant.
 - a. Go around the circle and ask each participant the following questions:

- i. What is one example of treatment advice that you have received from a doctor?
 - ii. What evidence did the doctor present in support of this advice?
 1. Ask questions to clarify if necessary.
 - b. Record each example of treatment advice with its related evidence on a flip chart. Post examples on the wall.
3. (15 minutes) Present the hierarchy of evidence
 - a. Provide a handout with each level of evidence defined.
 - b. Describe each level of evidence and give an example of each (theory, tradition and common sense; an animal study; an open-label trial; a randomized control trial; a systematic review; a clinical guideline). Show an article of each type.
4. (15 minutes) Discuss participants' desired information about level of evidence.
 - a. How much do you want to know about the level of evidence that supports your doctor's advice?
 - i. Ask the participants to write the answer to this question on 3x5 cards.
 - ii. Ask one participant at a time to read their answer. Gather answers on storyboard. Group them in categories.
 - b. Probe: Does your answer to this question vary with circumstances? If so, how? Circumstances might include the family member the treatment is proposed for, other family circumstances, your beliefs and values, etc.
 - i. Ask the participants to write the answer to this question on 3x5 cards.
 - ii. Ask one participant at a time to read their answer. Gather answers on storyboard. Group them in categories.
 - c. Probe: How can the doctor explain this in a way that makes sense to you?
5. (15 minutes) Explore the gap between evidence and patient/family values.
 - a. Describe the acknowledged gap between evidence and patient/family values, using the reverse-pyramid diagram that is on the participant's handout.
 - b. Ask the participants this question: In addition to evidence, what factors do you consider when making a medical decision regarding a treatment when *you* are the patient?
 - i. Write the group's list of factors on a flip chart.
 - ii. Ask each participant in the group to mark the three factors that are most important to him or her.
 - iii. Post this list on the wall.
 - c. Ask the participants this question: In addition to evidence, what factors do you consider when making a medical decision regarding treatment when your *child* is the patient?
 - i. Write the group's list of factors on a flip chart.
 - ii. Ask each participant in the group to mark the three factors that are most important to him or her.
 - iii. Post this list on the wall.

6. (15 minutes) Explore Number Needed to Treat (NNT) and Number Needed to Harm (NNH)
 - a. Explain NNT and NNH.
 - b. Ask the participants this question: Does the explanation (NNT and NNH) of risk help you make a decision about treatment? Why or why not?
 - c. Ask the participants to write the answer to this question on 3x5 cards.
 - d. ~~Ask one participant at a time to read their answer. Gather answers on storyboard. Group them in categories.~~
 - e. Probe: How can the doctor explain this concept in a way that makes sense to you?
 - i. Write on flip chart.
7. ~~(15 minutes) Explore different kinds of evidence.~~
 - a. ~~Describe kinds of evidence.~~
 - i. ~~Evidence about what works~~
 - ii. ~~Evidence about risks/side effects~~
 - b. ~~How do you balance evidence about what works with evidence about the risks of treatment when you make a medical decision?~~
8. (15 minutes) Explore how doctors make decisions
 - a. Use the intersecting circles diagram to explain how a doctor balances clinical judgment, evidence (both about what works and about risk), and patient/family values. Refer to handout.
 - b. Give participants a handout on which to rank order these three factors:
 - i. The doctors' clinical judgment
 - ii. The evidence (both what works and risk)
 - iii. The patient/family's values
 - iv. Other factors that have come up in discussion.
9. (15 minutes) Summative discussion
 - a. How can you and your doctor work together to balance the doctor's clinical judgment, the evidence, and your values?
 - b. Ask participants to write their answers on 3x5 cards. Share answers, post on storyboard and group the answers.
 - c. Probes:
 - i. What explanations of evidence do you want?
 - ii. What do you want the doctor to ask you?
 - iii. ~~What do you want to know about the doctor's clinical judgment?~~
 - iv. What can you do to let the doctor know what you want?

Homework:

Choose one:

- 1. Edit the handouts to make them patient-friendly.*
- 2. Write a story of one time you had to make a treatment decision and the factors you used, how you weighed them, and the role evidence played or didn't play.*

Appendix 4: Summary of Data Analysis

Question 2: Elicit a short example of treatment advice and related evidence from each participant.

- i. What is one example of treatment advice that you have received from a doctor?*
- ii. What evidence did the doctor present in support of this advice?*

These were anecdotal recollections from the parents and patients. Three of eleven received some evidence in the EBM context. However, the remainder received advice that was labeled by the physician as experience or opinion, which may indicate there was no evidence available or that there was evidence available but it was not shared. The recall bias and the nature of the topic for group discussion probably biased the recollections of the participants.

Question 4a: How much do you want to know about the level of evidence that support's your doctor's advice?

The first group wanted specific & detailed information about the research studies upon which the recommendation was being based. Several sought alternatives and specifically questioned basis of decision. Theme included questioning the source nature and reliability of evidence and several traditional versus alternative. The first group wants to know everything including primary sources to review conclusions. Could be interpreted as wanting to come to their own independent conclusion, as seeking to second guess the physician, and/or simply wanting to maximize to the fullest extent possible their understanding of the situation.

The second group generally also wanted similar overall information but in much less detail and did not question the underlying statistical analysis. This group appeared much less critical. It was not clear if some of the responses were what they wanted the decision to be based upon versus what they wanted to be told. They generally wanted to know what sources were used and to be informed of the basis of the physician's conclusions, but didn't want underlying data to second guess or question the underlying analysis.

Question 4b: Does your answer to this question vary with circumstances? If so, how?

The first group strongly emphasized desperation/emergency. With several noting that outside advice or trusted anecdotes might sway them. The nature of the outcome was noticed as strongly influencing several. One indicated physician trust.

The second group, trust in the physician was the major theme but wishes of the child also important. The other two focused on the issue of child vs. themselves.

The first groups emphasis on emergency as impacting the amount of information appears connected with the length of time needed to review the information provided (i.e. would they have time to process and analyze the information).

Question 5b. In addition to evidence, what factors do you consider when making a medical decision regarding a treatment when you are the patient?

Question 5c. In addition to evidence, what factors do you consider when making a medical decision regarding treatment when your child is the patient?

The first group seemed very focused primarily on family arrangements/family care and secondarily on impact on self when making a health care decision for SELF. They also mentioned gut instinct, intuition, and faith. When making a health care decision for their CHILD, the group focused on the fact that they would do whatever it takes to help their child. There was a lot of focus that they would do anything no matter what the consequences. Concern for family remained on the list, but less emphasis was placed on short run. When asked to rank order the factors most important to them for SELF, 8/10 mentioned family. In comparison, when ranking factors for their CHILD, 10/10 focused on some aspect of consequences (i.e. what if I don't do this, long term effect, etc.) Only one person mentioned practitioner for CHILD. They wanted the practitioner to be knowledgeable and have research done.

The second group was primarily very focused on relationship with the doctor when making decisions for SELF, specifically personality, rapport, professionalism, trust, etc. Secondly, this group was focused on impact on family. When making health care decisions for CHILD, this group focused on doing whatever it takes to help the child, however this group valued the child's opinion in the decision making process and also impact to family and career. When asked to rank order the factors most important to them for SELF, 4/5 focused on factors affecting themselves, fewer mentioned impact on family (3/5). In comparison, when developing a rank order for the CHILD, 4/5 focused on the doctor's opinion for the child, followed by a secondary aspect of child's quality of life. There was less emphasis on consequences when compared to the first group.

Both groups indicated some sort of risk/benefit analysis not as primary theme, but present in both listings for SELF. Both groups also focused on whatever it would take for CHILD as a primary theme for both.

Question 6. Does the explanation (NNT and NNH) of risk help you make a decision about treatment? Why or why not?

A few indicated they would take it into consideration, but overall they did not appear to place much value in it, with one group member describing it as confusing. They do, however, want some discussion of benefits and risks, and, for some, the more serious the condition, the more the need to know these statistics plus any others available. Some also indicated they wanted the physician's "common sense" explanation.

Question 6e. How can the doctor explain the concept (NNT/NNH) in a way that makes sense to you?

Both groups agreed that the word "harm" should be relabeled in discussions as "side effects" and that the "need to" gave a negative connotation to the concept.

Most wanted all the information regardless of their emotional state at the time. Most want the doctor to check back to ensure understanding. Most wanted all the information including multiple approaches to communicating risk. They also felt that deciding on the seriousness of the risks or "harms" was their responsibility.

One wrote the "ideal script" "I'd like to share some evidence with you about your/your child's situation so you feel fully informed and we can come up with a good plan."

Question 8b. Give participants a handout on which to rank order these three factors:

- i. The doctor's clinical judgement*
- ii. The evidence (both what works and risk)*
- iii. The patient/family's values*
- iv. Other factors that have come up in discussion*

The overall ranking for the first group was Evidence #1, Doctor's Judgment #2, and Patient/Family Values #3. Also for the three people who specifically mentioned children, the ranking was exactly the same: Evidence #1, Doctor's Judgment #2, and Patient/Family Values #3.

For the second group, Evidence was either placed 1st or 3rd while Doctor's Judgment was placed 2nd and Patient/Family Values was placed 3rd. However the ranking was less clear with this group, probably due to the small number of participants.

Evidence was more important in the first group and factors rated relatively evenly in the second group. However, this question is problematic because the topic of EBM in discussion in the groups may have biased each group towards evidence.

Question 9. How can you and your doctor work together to balance the doctor's clinical judgment, the evidence, and your values?

- i. What explanations of evidence do you want?*

The major theme from both groups appears to be emphasis on risk v. benefit. The first group tended to emphasize desiring a complete and detailed explanation. The second group kept the description of their desired explanation more general.

- ii. What do you want the doctor to ask you?*

The first group placed a strong emphasis on wanting the doctor to ask them if they understand and whether they needed additional information or assistance.

The second group primarily focused on wanting the doctor to ask about their fears or impact on life.

iii. What can you do to let the doctor know what you want?

The first group placed emphasis on asking questions, being assertive, and discussing options to ensure their own understanding.

The second group emphasized sharing information, concerns and wants with the physician to ensure that they get needed information to the physician.

Appendix 5: Demographic Tables

Table 1: Characteristics of participants gathered during phone interviews	
Number completed	30
Number willing to participate in focus groups	26 (87%)
Approximate length of time dealing with health care need	2-28 years (average 11 years)
Average years of education past high school	5 years
Gender	
Male	5
Female	21

Table 2: Characteristics of Focus Groups	
Focus Group #1 ("Statistics")	
Number willing to participate	19
Number able to participate	9 (+1 additional arrival)
Average years of education past high school	4.6 years
Gender	
Male	1
Female	9
Focus Group #2 ("Relationships")	
Number willing to participate	7
Number able to participate	4 (+1 additional arrival)
Average years of education past high school	3.7 years
Gender	
Male	2
Female	3

Appendix 6: Focus Group Handouts

Evidence-Based Medicine

Definition from the Physician's Point-of-View

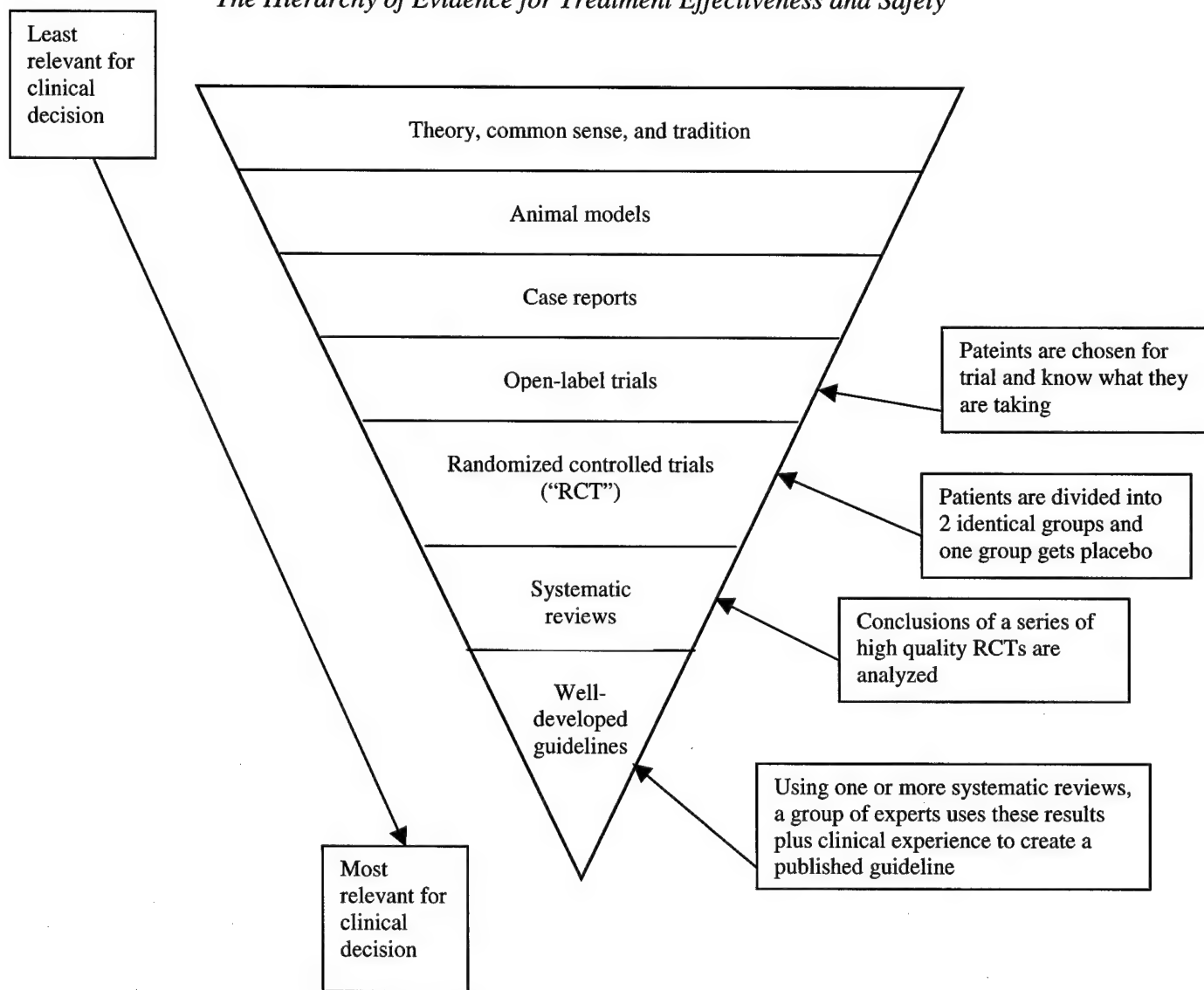
A method for making clinical decisions that incorporates the highest level of evidence applicable to the patient.

Steps:

1. Define problem: define patient population, treatment, outcome.
2. Computer search of databases and articles for highest level of evidence.
3. Critical appraisal of article.
4. Determine if applies to patient.
5. Share with patient.
6. Taking into account patient's values and preferences, make decision.

Evidence-Based Medicine

The Hierarchy of Evidence for Treatment Effectiveness and Safety



patient

Evidence-Based Medicine

Treatment Effectiveness and Safety: Balancing Benefit and Risk

Number Needed to Treat (“NNT”): The number of patients who need to receive the treatment in order that one patient benefit.

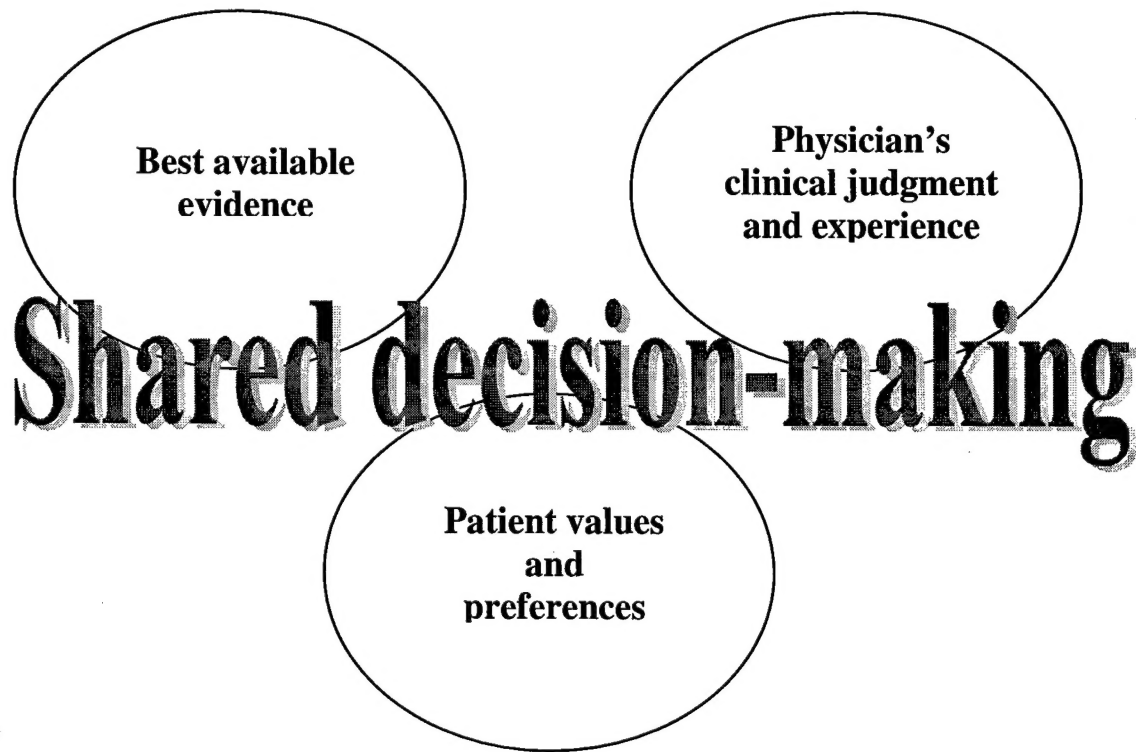
Number Needed to Harm (“NNH”): The number of patients who need to receive the treatment in order to produce side effects in one patient.

NNT and NNH are calculated from the results of RCTs. They are helpful for clinical decisions because they demonstrate the relative values of risk and benefit.

For example, one study investigated whether using valium at the first sign of fever in a toddler who has had a previous febrile seizure would decrease the recurrence of febrile seizures. The RCT concluded that the recurrence was reduced and valium should be used this way. It has previously been shown that recurrent febrile seizures do not harm the child and do not lead to epilepsy. When the NNT and NNH were calculated, it was found that $NNT = 13$ and $NNH = 3$. This means that 13 children need to be treated to prevent one febrile seizure and of those treated, 1 in 3 would experience a “moderate” side effect. Thus, the NNT and NNH put the benefit/risk into perspective.

Evidence-Based Medicine

Shared-Decision Making



Put these factors into rank order with #1 the most important:

_____ Doctor's clinical judgment and experience

_____ The evidence (benefit/risk)

_____ Patient and family values and preferences

Appendix 7: Flow Chart for Physicians

